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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,867	02/04/2002	Halle Morton	999710000008	3108
7590 Kate H Murashige Morrison & Foerster Suite 500 3811 Valley Center Drive San Diego, CA 92130-2332			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT 1647	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
3 MONTHS			01/09/2007	
			DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/889,867	<b>Applicant(s)</b> MORTON ET AL.	
	<b>Examiner</b> Jegatheesan Seharaseyon, Ph.D	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,25,27-30,32-39,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3-11, 25, 27-30, 32-39 and 43-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This Office Action is in response Applicants remarks and amendment filed 10/20/2005. Claims 1, 3-11 and 25-42 are pending. Claims 43 and 44 have been added. Claims 26, 31 and 40-42 are cancelled. Thus, claims 1, 3-11, 25, 27-30, 32-39 and 43-44 are pending and under consideration in this action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn

#### ***Claim Rejections - 35 USC § 103, maintained***

4. The rejection of claims 1, 3-11, 25, 27-30 and 32-39 and 43-44 (newly added) under 103(a) as unpatentable over Morton et al. (WO 95/15338) in view of the M.S. study (Neurology, 1993) is maintained for reasons of record in the Office Actions dated 5 August 2003, 5 October 2004, 27 April 2005, 1 February 2006 and 16 June 2006 and is applied to new claims 43-44. Applicants have incorrectly indicated that claims 37-39 were not under this rejection (see page 7 of the response). Applicants advised to review the Office Action of 16 June 2006 page 2, paragraph 4 for the applicable rejection. It is noted that after the entry of the amendment claim 26 remains cancelled.

The claims require treating multiple sclerosis by administering cpn10 and IFN- $\beta$ , wherein the therapeutic effect of administering cpn10 and IFN- $\beta$  together is improved compared to therapeutic effect of administering the same equivalent amount cpn10 or IFN- $\beta$  alone. Applicants assert that neither the Morton reference nor the MS study, nor

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the combination thereof, teaches or suggests that combined cpn10 and IFN- $\beta$  treatment of MS or delay relapse following cessation of other treatments. Applicant's arguments have been fully considered but are not found to be persuasive.

Applicant has modified the claims to remove the assertion that cpn 10 or IFN- $\beta$  in combination produced synergistic effect (page 9 of the response). However, Applicant asserts that the invention provides methods of treating MS in an individual taken off IFN- $\beta$  treatment or having reduced dose IFN- $\beta$  treatment because of IFN- $\beta$ -induced side effects, by administering to an individual in need thereof a combination treatment comprising pharmaceutically effective amounts of both cpn10 and IFN- $\beta$ , wherein the IFN- $\beta$  is administered at a dose that does not produce IFN- $\beta$  induced side effects in the individual. As argued previously in the Office Action dated 6/16/2006 (pages 4-5) the dosages of cpn10 and IFN- $\beta$  disclosed in Morton et al. and the MS study are within the doses contemplated in the instant invention. For example, Morton on page 27 discloses cpn10 doses of 1-1000 $\mu$ g/kg of body weight and more preferably 50-200 $\mu$ g/kg of body weight encompasses the 10-30 mg of cpn10 contemplated in the instant invention. In addition, the IFN- $\beta$  doses disclosed in the MS study group (1.6 MIU and 8 MIU) are similar to those contemplated in the instant invention.

Applicant argues that administering a drug at dosages, which, if not administered in combination with a second, different drug, would be ineffective, is a significantly different fact pattern than "optimizing" an otherwise clinically effective dose at dosages. Applicant further contends administering a drug at a clinically ineffective dose is not merely "optimizing a workable range" by routine experimentation. The MS study group

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used 1.6MIU and 8MIU, which is within the "suboptimal dose" contemplated by the Applicant (1-10MIU). Furthermore, the 1.6MIU of IFN- $\beta$  used in the MS study is much lower than 4-6MIU recited in the claims and less than optimum compared to 8MIU administration (page 660). The MS study also discloses that 16MIU produced unacceptable toxicity (page 660). Therefore, *In re Aller* fact pattern is applicable to the administration of IFN- $\beta$  because it is routine in the art to optimize the dosage administered to a patient obtain optimal clinical outcome and thus not inventive. Applicant's arguments to "clinically ineffective" dose are misplaced because this is not a limitation of the claims. In addition, suboptimal dose does not equal to clinically ineffective dose. Furthermore, contrary to Dr. Johnson's declaration and argued by the Applicant that there was no understanding or teachings in the art at the time of the invention to lower an otherwise toxic and clinically ineffective dose of IFN- $\beta$  and then combine the dose with cpn10 to realize an effective therapy for MS, the MS study clearly discloses reduced doses of IFN- $\beta$  to reduce the toxicity. This in combination with Morton's teaching will make the instant invention obvious over prior art.

Although, Applicant asserts on page 11 that all claims directed to an active from inactive state of MS have been cancelled, the newly added claim 44 recites this limitation. The Office Action dated 6/16/2006 addressed the issues pertaining to relapse (see pages 3-6). Applicant is also arguing that there was long felt need to administer both cpn10 and IFN- $\beta$ . Applicant analyses MPEP § 716.04 to address issues relating to long-felt need in the art. As stated previously (Office Action of 6/16/2006, page 6), declaration under 37 CFR 1.132 is insufficient to overcome the obviousness rejection,

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because there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. Specifically data shows very little advantage to the combination therapy to that of administering cpn10 or IFN- $\beta$  alone. Therefore does not meet the long-felt need in the art. Therefore, the rejection of record is maintained.

### **Conclusion**

5. No claims are allowable.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
Art Unit 1647  
December 27, 2006

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*